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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/771,804	02/04/2004	Wilfred J. Samson	CARDE.63292	3336

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EXAMINER

MARCETICH, ADAM M

ART UNIT	PAPER NUMBER
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3761

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/05/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/771,804

Applicant(s)

SAMSON ET AL.

Examiner

Adam Marcetich

Art Unit

3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on _____ is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Claim 26 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 13 November 2006. Claims 1-25 are considered as the elected invention.

Priority

2. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

3. The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

4. The disclosure of the prior-filed application, Application No. 10/102124, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. Abandoned application

10/102124 lacks the disclosure of an apparatus having side-by-side supply and return lumens. Application 10/102124 also lacks a needle valve. Therefore, priority of the prior application is not given.

Specification

5. The disclosure is objected to because of the following informalities: continuity data should be updated by the applicant on the first page of the specification.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim 5 recites the limitation "said distal end." There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-4, 9, 11-13 15 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Saab (US Patent Application Publication No. 2002/0045852).
10. Regarding claim 1, Saab discloses a distal port (Fig. 3, element 70 and paragraph [0053]). Saab also discloses delivering fluid to the surrounding tissue (Fig. 6, elements 252 and 254 and paragraphs [0037] and [0059]).
11. Regarding claims 2 and 15, Saab discloses the lumens as coaxially arranged (Fig. 3 and paragraph [0043]).
12. Regarding claim 3, Saab discloses the lumen as being disposed within the return lumen (Fig. 3, elements 64 and 68 and paragraph [0065]).
13. Regarding claims 4 and 16, Saab discloses a valve for adjusting both the first and second fluid flow portions (paragraph [0046]).
14. Regarding claim 9, Saab discloses the flow in the supply lumen as being generated by positive pressure in the supply lumen (paragraph [0055]).
15. Regarding claim 11, Saab discloses a catheter for cooling or heating tissue (paragraph [0023]), comprising an inner lumen for delivering fluid (Fig. 3, element 64 and paragraph [0053]) and an outer lumen for fluid return (Fig. 3, element 68 and paragraph [0053]).
16. Regarding claim 12, Saab discloses the second flow as containing portions of the first flow (Fig. 3, elements 64 and 68).
17. Regarding claim 13, Saab discloses the second flow as being directed away from the patient's tissue (Fig. 3, element 68).

Claim Rejections - 35 USC § 103

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

19. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

20. Claims 5-7 and 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saab in view of Baran (US Patent 6,729,334). Saab solves the problem of cooling a body region with a catheter.

21. Regarding claims 5, 7, 17, 18, 19, Saab lacks a valve at the distal end of the catheter. Baran discloses a needle valve at the end of a catheter (Fig. 19, elements 284 and 286 and column 17, lines 14-19) for the purpose of adjusting medication delivery (column 17, lines 19-32). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the catheter of Saab with the needle valve of Baran in order to regulate medication delivery as called for by Baran.

22. Regarding claim 6, Saab lacks a valve adjustable from the proximal end of the catheter. Baran discloses a needle valve adjustable from the proximal end (Fig. 19,

element 293 and column 17, lines 9-12). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the catheter of Saab with the needle valve of Baran in order to regulate medication delivery as called for by Baran.

23. Claims 8 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saab and Baran in view of Chin (US Patent 4,318,410). Saab and Baran lack a slide valve. Chin discloses catheter having a slide valve (column 2, lines 39-44 and column 3, line 48, claim 1). Chin solves the problem of placing a catheter within the body and injecting liquid (abstract). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the catheter of Saab and Baran as discussed with the slide valve of Chin in order to provide a means of controlling the administration of cooling fluid.

24. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Saab in view of Stevens et al. (US Patent Application Publication No. 2001/0044591). Saab lacks negative pressure assisting fluid in the return lumen. Stevens discloses a cardioplegia catheter (abstract) which can be used to apply negative pressure (paragraph [0032]). The negative pressure can also be used to return blood or fluid to the pumping system after it has cooled (paragraph [0165]). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to

combine the catheter of Saab with the negative pressure of Stevens in order to provide a means of returning fluid to the pumping system as called for by Stevens.

25. Claims 14 and 21-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saab in view of Epstein (US Patent 6,471,667).

26. Regarding claim 14, Saab lacks a catheter that delivers a difference between first and second flows to tissue. Epstein discloses a medical suctioning device that delivers adhesive while applying variable suctioning to remove clotted adhesive (column 6, lines 10-25 and Fig. 1, elements 10, 12, 14 and 16). The remainder of adhesive not aspirated back into the device remains on the patient (Fig. 1, element 16). Epstein solves the problem of administering and aspirating a substance from a patient for the purpose of preventing excess accumulation (column 6, line 17). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the catheter of Saab with the variable suction of Epstein in order to prevent excess accumulation as called for by Epstein.

27. Regarding claim 21, Saab discloses a catheter for exchanging heat with tissue, having lumens for delivering and returning fluid as discussed in paragraph 12 above. Saab lacks a portion of flow expelled into tissue. Epstein discloses a medical suctioning device having both delivery and suction lumens as discussed in paragraph 26 above. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the catheter of Saab with the suctioning and aspiration of Epstein. With respect to rationale and motivation, see paragraph 26 above.

28. Regarding claim 22, Saab lacks an adjustable flow of expelled fluid. Epstein discloses adjustable suction for the purpose of regulating how much adhesive remains on the patient (column 6, lines 10-25). With respect to rationale, see paragraph 26 above.

29. Regarding claim 23, Saab discloses a cooling catheter having supply fluid conducted towards the patient and return fluid conducted away from the patient (Fig. 3, elements 64 and 68 respectively). Saab lacks adjusting the portion of fluid expelled from the catheter. Epstein discloses adjustable suction as discussed in paragraph 26 above. With respect to motivation, see paragraph 26 above.

30. Regarding claims 24 and 25, Saab discloses a cooling catheter having supply and return lumens as discussed in paragraph 3 above. Fluid flowing towards the patient is surrounded by fluid returning from the patient. Since heat needs to pass through the returning flow of fluid before reaching the inner supply flow, the outer return flow effectively insulates the inner supply flow.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Adam Marcetich whose telephone number is 571-272-2590. The examiner can normally be reached on 8:30am to 5:00pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone

Art Unit: 3761

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Adam Marcetich
Examiner
Art Unit 3761

Adam Marcetich

AMM 1/30/07

TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER

Tatyana Zalukaeva